

### REMARKS

Reconsideration and withdrawal of the objection to and rejections of the claims, in view of the amendments and remarks herein, is respectfully requested. Claims 57, 62 and 67 are amended, claims 77-78 are added, and claim 65 is canceled. The amendments are intended to advance the application and are not intended to concede to the correctness of the Examiner's position or to prejudice the prosecution of the claims present prior to amendment, which claims are in a continuing application of the above-referenced pending application. Claims 57-64, 67-68 and 71-78 are now pending in this application.

The cancellation of claim 65 and the amendment to claim 67 address the objections to claims 65 and 67.

#### The 35 U.S.C. § 112 Rejections

Claims 57-65, 67-68 and 71-76 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (a "new matter" rejection). This rejection, as it may be maintained with respect to the pending claims, is respectfully traversed.

In particular, the Examiner asserts that the specification does not support the following phrases: "co-culturing on solid media monocot plant tissue or cells and an *Agrobacterium*," "co-culturing on solid media plant tissue or cells and an *Agrobacterium*" and "wherein if the sulfhydryl-containing agent is cysteine, cysteine is present at a concentration of 50 mg/L to 2000 mg/L".

Support for co-culturing plant cells or tissue, including monocot cells and tissue, on solid media with *Agrobacterium* is found, e.g., at pages 6 and 14 (page 14 discloses that the invention provides a method for the genetic modification of plants, both monocots and dicots, via *Agrobacterium*-mediated or other methods), in the Examples (see page 55), and in originally filed claims 15 and 37. For example, at page 6, it is disclosed that the addition of the sulfhydryl compound L-cysteine to the co-cultivation media during the 5-day incubation step on solid co-culture media, which occurred after contacting the wounded explant with *Agrobacterium* in liquid co-culture for about one half of an hour, resulted in increased numbers of transformed cells.

Support for concentrations of cysteine in solid media is found in the Examples (for instance, see page 65, Figures 9 and 10B, and originally filed claims 49-50 and 52-53).

Accordingly, withdrawal of the § 112, first paragraph, “written description” rejection is respectfully requested.

Claims 57-61, 63-65, 67-68, and 71-76 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. This rejection is respectfully traversed.

Specifically, the Examiner asserts that Applicant has not reduced the invention to practice, as the specification does not disclose media or transformation protocols specific to monocots tissues or cells.

To support the assertion that the specification does not enable the use of *Agrobacterium* for all plants or plant tissues, the Examiner cites Hansen et al. (Trends in Plant Sci., 4:226 (1999)). The last paragraph at page 227 which overlaps to page 228 of Hansen et al. states that successful transformation of plants requires target tissues competent for propagation, an efficient DNA delivery system, agents to select for transgenic tissues, the ability to recover fertile transgenic plants at a reasonable frequency, a simple, efficient, reproducible, genotype-independent and cost-effective process, and a tight timeframe in culture to avoid somaclonal variation. Hansen et al. state that “[a]t present, three techniques appear to fulfill these criteria,” one of which is *Agrobacterium*-mediated transformation.

In fact, *Agrobacterium* has been used to transform a broad range of host plant species. For example, Hansen et al. discuss *Agrobacterium*-mediated transformation of dicots (page 228), methods of overcoming *Agrobacterium*-mediated necrosis in grape and *Populus* (page 228), and successful *Agrobacterium*-mediated transformation of the monocots barley, wheat, maize, and sugarcane (page 229). Thus, in contrast to the Examiner’s characterization of the paragraph bridging pages 228-229 of Hansen et al. (“she teaches that many plants are recalcitrant and defend themselves well against *Agrobacterium*”, page 3 of the Office Action), Hansen et al. support the position that *Agrobacterium* transforms many types of plants, including monocots. Moreover, Perl et al. (Biotechnology, 14:624 (1996)), a reference cited against the claims under 35 U.S.C. § 102(b), notes that *Agrobacterium* has an “extraordinarily broad host range” in higher plants (page 625).

Clearly, methods of using *Agrobacterium* to transform a wide variety of plants including monocots were well-known to the art prior to Applicant's filing. See, e.g., Enriquez-Obregon et al. (Biotechnologia Aplicada, 14:169 (1997); transformed sugarcane), a reference cited against the claim under 35 U.S.C. § 103, and the abstracts for Lynch et al. (J. Econ. Entomol., 92:246 (1999); transgenic corn), Schenk et al. (Plant Mol. Biol., 39:1221 (1999); transgenic banana), Srivastava et al. (Proc. Natl. Acad. Sci. USA, 96:11117 (1999); transgenic wheat), and Kohli et al. (Plant J., 17:591 (1999); transgenic rice) (a copy of each is enclosed herewith). Applicant need not teach what is well-known to the art. Hybritech Inc. v. Monoclonal Antibodies, Inc., 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986).

Therefore, withdrawal of the § 112, first paragraph, enablement rejection is respectfully requested.

The 35 U.S.C. § 102 Rejection

Claims 58-65, 67-68 and 71-74 were rejected under 35 U.S.C. § 102(b) for anticipation by Perl et al. (Biotechnology, 14:624 (1996)). This rejection, as it may be maintained with respect to the pending claims, is respectfully traversed.

Perl et al. disclose that short exposures of diluted cultures of *Agrobacterium* to embryogenic calli of *Vitis vinifera* cv. Superior Seedless grape result in plant tissue necrosis and subsequent cell death (abstract). To determine the effect of various antioxidants on necrosis, Perl et al. added antioxidants to the solid co-cultivation medium (treatments 1-6 in Table 1). Perl et al. relate that the presence of polyvinyl pyrrolidone (PVP), cysteine, ascorbic acid, or citric acid in the solid co-cultivation medium was unable to reduce necrogenesis, while the presence of dithiothreitol (DTT) or polyvinyl polypyrrolidone (PVPP) in the solid co-cultivation medium reduced browning to some extent but did not completely inhibit the phenomenon (page 625). Note that Perl et al. report that the presence of cysteine, a sulfhydryl containing agent, in the solid co-cultivation did not reduce necrogenesis.

Perl et al. also relate that an optimal effect in blocking necrogenesis was obtained with a double-layer medium containing PVPP and DTT, but that necrosis was not blocked when a double-layer medium with PVP, ascorbic acid, or cysteine in the solid medium, with or without DTT in the liquid medium, was employed (page 625). It is disclosed that stably transformed

grape was obtained after co-cultivation of grape callus with PVPP for 48 hours, followed by incubating the callus in a double-layer medium with PVPP in the solid layer and DTT in the liquid layer for 7 days (Figure 3).

Thus, the use of cysteine and DTT (both sulfhydryl containing agents) in Perl et al. resulted in disparate results.

Moreover, the use of cysteine in solid media (10-200 mg/L for 48 hours or for 7 days with a DTT liquid overlay) in Perl et al. did not reduce or block grape calli necrogenesis. Cells that die cannot form the basis for stable transformants.

Therefore, Perl et al. do not teach an amount of cysteine in solid co-cultivation media that can enhance Agrobacterium-mediated stable transformation of plant tissue or cells.

Accordingly, withdrawal of the § 102(b) rejection is respectfully requested.

#### The 35 U.S.C. § 103 Rejection

Claims 57-65, 67, 71-73, and 75-76 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Enriquez-Obregon et al. (*Biotechnologia Aplicada*, 14:169 (1997)) taken with Hansen et al. (*Trends in Plant Science*, 4:226 (1999)). This rejection, as it may be maintained with respect to the pending claims, is respectfully traversed.

Enriquez-Obregon et al. report on the effect of three antioxidants on the growth of *Agrobacterium* in sugarcane. It is disclosed that a combination of ascorbic acid (15 mg/L), cysteine (40 mg/L) and silver nitrate (2 mg/L) was added to the precoculture liquid medium and the solid medium. After 3 days on solid media, explants were placed on selective media and the number of transformants determined (Table 2). It is disclosed that an efficient regeneration technique results in transgenic plants from the transformed explants, however, no data on those plants is provided in the Enriquez-Obregon et al. article.

Hansen et al. is discussed above.

It is unclear from the disclosure in Enriquez-Obregon et al. whether cysteine alone in the solid medium, and at what concentration, would result in enhanced stable transformation. Moreover, given that the use of cysteine in solid media in Perl et al. did not reduce or block grape calli necrogenesis, one of skill in the art in possession of Enriquez-Obregon et al. would not be motivated to use cysteine in solid co-cultivation media to enhance stable transformation or

have a reasonable expectation there are amounts of cysteine that, when present in solid media, enhance stable transformation of plant tissue or cells.

With regard to the amount of cysteine recited in the claims, the Examiner is requested to reconsider the Rule 132 Declaration enclosed with the Amendment filed on April 1, 2008. In that Declaration, Dr. Olhoft states that when any agent is added to plant media in an effort to improve outcome, there is a balance between plant cell viability and agent toxicity, for instance, at one concentration, the agent may not substantially impact plant cell viability while at a higher concentration the agent may decrease plant cell viability. Dr. Olhoft concludes that in view of the balance between plant cell viability and agent toxicity, and *Agrobacterium*-mediated virulence, there would be no reason to try higher amounts of any of the agents in the combination disclosed in Enriquez-Obregón et al. because of potential cytotoxicity.

Therefore, withdrawal of the § 103(a) rejection is respectfully requested.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date

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**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 17<sup>th</sup> day of August, 2008.

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